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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,304

06/27/2003

Michel J. N. Cormier

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06/14/2006

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/608,304	CORMIER ET AL.	
Examiner	Art Unit	
James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23 are pending.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks PLURONIC® [00022] and TWEEN® [00022] have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9, 11, 13, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 11, 13, 18, and 20 are vague and indefinite because they utilize a trademark (i.e. TWEEN® and PLURONIC®) to refer to a component of the recited composition, which is improper. Trademarks are associated with goods and services, which may change at any time

based upon the manufacturers prerogative. Therefore, they are inherently indefinite, when used to refer to a composition of matter. See MPEP § 2173.05 (u).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, 12, 15-16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630).

Applicant Claims

Applicant claims a method of coating the surface of one or more microprojections or a microprojection array comprising (1) providing a microprojection array; (2) providing a coating formulation comprising an active agent and a wetting agent; (3) applying said coating formulation to one or more microprojection surfaces; (4) drying said coating formulation onto said surface; and (5) treating the surface of said microprojections with a method selected from pre-etching, plasma treatment, heating treatment, rinsing with an alkaline solution, and rinsing with a wetting agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Trimmer teaches a method of introducing a biological material (i.e. active material) into a predetermined target cell population comprising providing (a) a plurality of inert microprobes (i.e. microprojections) positioned on a support (i.e. an array), (b) a solid or quasi-solid mass of target cells defining an interface with the microprobes, and (c) a biological material at the interface, and the physically contacting the cells with the microprobes to cause the microprobes to non-lethally pierce the cell walls and/or membranes of the cells. The target cells may be contacted by the microprobes *in vitro* or *in situ*. This method is applicable to virtually all cell types and any biological material capable of being introduced into cells described therein (abstract). **The biological materials can be applied to the microprobes and/or support or**

substrate in several ways, including the direct deposition of a film or coating with standard techniques (pg. 11, lines 24-31). Trimmer speculates that any liquid material, which wets the substrate surface, will be trapped as a meniscus between the microprobes and this effect can be enhanced by adding wetting agents to the solution of biological material, or to the medium in which the method is carrier out (pg. 11, line 35 through pg. 12, line 3). In Example 1, Trimmer teaches the fabrication of the microprobes from silicon wafers including the following steps: (1) cleaning with a mixture of HCl and hydrogen peroxide (i.e. a wetting agent); (2) oxidation by heating in an electrically heated quartz furnace; (3) etching in buffered hydrofluoric acid; (4) cascade rinsing; and (5) etching in an aqueous solution of KOH (i.e. an alkaline solution).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Trimmer does not anticipate the cited claims in the instant rejection, because Trimmer does not teach drying the coating formulation.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been apparent to a person or ordinary skill in the art at the time of the instant invention that Trimmer's method is obvious over that recited by claims 1-3, 5-7, and 15-16. The step of drying a coating formulation is a conventional step (see, for example, claim 15 of WO 02/07813). It would have been apparent to a person of ordinary skill in the art at the time of the instant application that to form a film or coating from the application of a liquid formulation requires the step of drying said formulation. It would also have been obvious to a

person of ordinary skill that the term “biological material,” which Trimmer teaches can be applied as a film or coating onto his invented microprobes, includes proteins and peptides. Proteins and peptides are art recognized biological materials. A skilled artisan would have had a reasonable expectation of successfully forming a film of the biological materials taught by Trimmer on his invented microprobes, because the step of drying a coating formulation is conventional.

Claims 8-10, 13, 17-19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Baum (U.S. Patent No. 6,294,515).

Applicant Claims

Applicant claims a method of coating the surface of one or more microprojections or a microprojection array comprising (1) providing a microprojection array; (2) providing a coating formulation comprising an active agent and a wetting agent; (3) applying said coating formulation to one or more microprojection surfaces; (4) drying said coating formulation onto said surface; and (5) treating the surface of said microprojections with a method selected from pre-etching, plasma treatment, heating treatment, rinsing with an alkaline solution, and rinsing with a wetting agent, wherein the wetting agent is a surfactant (e.g. TWEEN[®]).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Trimmer have been set forth above. Baum teaches low foaming rinse agents comprising alkylene oxide modified sorbitan fatty acid ester and defoaming agent (title and abstract). TWEEN[®] is a sorbitan and is an example of the alkylene oxide modified sorbitan fatty acid ester taught by Baum (col. 4, lines 37 through col. 5, line 13; col. 5, lines 25-36; Table IV), wherein specific TWEEN[®]s are TWEEN 20[®], TWEEN 60[®], and TWEEN 80[®]. TWEEN[®]s are surfactants and wetting agents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Trimmer lacks the teaching of surfactants (e.g. TWEEN 80[®]). This deficiency is cured by the teachings of Baum.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Trimmer and Baum, because Trimmer suggests that the inclusion of wetting agents to the solution of biological material, or to the medium in which the method is carrier out would enhance the wetting of the surface of his invented microprobes via the formation of a meniscus. Trimmer's suggestion to include wetting agents to the solution of biological material used to coat his invented microprobes would have provided the artisan with the motivation to combine the teachings of Trimmer and Baum, because surfactants are wetting agents and Baum teaches rinse agents comprising surfactants (i.e. wetting agents). A skilled artisan would have had a reasonable expectation of success upon combination because

TWEEN[®]s are well-known surfactants. The critical micelle concentration (CMC) of many surfactants and the methods needed to ascertain said concentrations are known in the art. It would have been well within the skill of the artisan to determine the CMC and use said concentration of a known surfactant within a formulation (See, for Example, Dominguez et al. "Determination of Critical Micelle Concentration of Some Surfactants by Three Techniques," *J. Chem. Educ.* **1997**, 74(10), 1227 (Abstract)).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Heinz et al. (US 2002/0012741).

Applicant Claims

Applicant claims a method of coating the surface of one or more microprojections or a microprojection array comprising (1) providing a microprojection array; (2) providing a coating formulation comprising an active agent and a wetting agent; (3) applying said coating formulation to one or more microprojection surfaces; (4) drying said coating formulation onto said surface; and (5) treating the surface of said microprojections with plasma treatment.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Trimmer have been set forth above. Heinz teaches a process and apparatus for applying a thermally attached lubricating coating on an interior wall of a cylindrical container for medical purposes (title & abstract). Heinz teaches that plasma

treatment is a conventional step in the pre-conditioning of a surface prior to surface coating [0010].

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Trimmer lacks the teaching of plasma treatment. This deficiency is cured by the teachings of Heinz.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Trimmer and Heinz, because Trimmer teaches the preparation of coated microprobes from silicon wafers comprising several pre-conditioning steps. The motivation to combine Heinz and Trimmer comes from the teaching that plasma treatment is a convention surface pre-conditioning step (Heinz). A skilled artisan would have had a reasonable expectation of success upon modification of Heinz' pre-conditioning steps taught in Example one to utilize plasma treatment, because plasma treatment is a conventional surface pre-conditioning step prior to the addition of a coating or film material.

Claims 11, 14, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Jain et al. (U.S. Patent No. 4,505,890).

Applicant Claims

Applicant claims a method of coating the surface of one or more microprojections or a microprojection array comprising (1) providing a microprojection array; (2) providing a coating formulation comprising an active agent and a wetting agent; (3) applying said coating formulation to one or more microprojection surfaces; (4) drying said coating formulation onto said surface; and (5) treating the surface of said microprojections with a method selected from pre-etching, plasma treatment, heating treatment, rinsing with an alkaline solution, and rinsing with a wetting agent, wherein the wetting agent is selected from HEC, HPC, HPMC, MC, HEMC, EHEC, and PLURONIC[®]s.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Trimmer have been set forth above. Jain teaches a coating composition in his Example comprising wetting agents, including hydroxypropylmethyl cellulose (HPMC) and ethyl cellulose (EC).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Trimmer and Jain, because Trimmer suggests that the inclusion of wetting agents to the solution of biological material, or to the medium in which the method is carried out would enhance the wetting of the surface of his invented microprobes via the formation of a meniscus. Trimmer's suggestion to include wetting agents to the solution of biological material used to coat his invented microprobes would have provided the artisan

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with the motivation to combine the teachings of Trimmer and Jain, because HPMC is a wetting agent and Jain teaches a coating composition comprising HPMC. A skilled artisan would have had a reasonable expectation of success upon combination because HPMC is a well-known compound used in coating formulations, and Trimmer suggested the inclusion of wetting agents in coating formulations comprising a biological material.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, and 15-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,855,372 (USPN ‘372) in view of Trimmer et al. (WO 96/10630). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Both USPN ‘372 and the instant application recite

methods of coating microprojections on a substrate (i.e. on an array) comprising the steps of (1) providing a coating formulation, (2) applying the coating to the microprojections, and (3) drying the coating formulation. It is obvious that the coating formulations of USPN '372 comprise an active agent, because Example 3 in USPN '372 teaches that several coating experiments were performed with several drugs and model compounds. The primary step missing from USPN '372 is the step of treating the surface of said microprojections. This deficiency is cured by the teachings of Trimmer et al. as set forth above in the instant office action.

Claims 1-3 and 15-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-30 and 33-38 of copending Application No. 10/674,626 (copending '626). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Both copending '626 and the instant application recite methods of comprising the steps of (1) treating the surface of one or more microprojections by etching (2) providing a coating formulation, (3) applying the coating to the microprojections, and (4) drying the coating formulation. The coating formulations of copending '626 comprise an active agent. The difference between the claims of copending '626 and the instant application is that the cited claims of copending '626 recite a method of making a device for transdermally delivering a biologically active agent and the claims of the instant application recite methods of coating microprojections. The practice of the method of copending '626 obviously results in the preparation of microprojections that are treated (i.e. etched), coated with

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a coating formulation, and dried. Therefore, the method of claims 29-30 and 33-38 copending '626 incorporate the steps of coating recited in the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-23 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

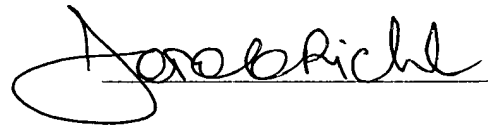
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line.

Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
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